TITLE OF THE INVENTION

Variable Angle Locked Bone Fixation System.

5

CROSS - REFERNCE TO RELATED APPLICATIONS

U.S. Patent Document

4,484,570	November, 1984	Sutter , et al.
5,053,036	October, 1991	Perren, et al.
5,151,103	September, 1992	Tepic, et al.
5,269,784	December, 1993	Mast, Jeffrey W.
5,607,426	March, 1997	Ralph, et al.
5,954,722	September, 1999	Bono
6,423,064	July, 2002	Kluger
6,454,769	September, 2002	Wagner, et al.
6,454,770	September, 2002	Klaue,Kaj
6,565,569	May, 2003	Assaker , et al.
6,575,975	June, 2003	Brace, et al.
6,623,486	September, 2003	Weaver, et al.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

REFERENCE TO SEQUENCE LISTING, A TABLE, OR A COMPUTER PROGRAM LISTING COMPACT DISC APPENDIX

Not applicable

BACKGROUND OF THE INVENTION

The present invention is directed to a locked bone fixation assembly, and in particular to an assembly that allows for a surgeon-selected angle of the bone screw relative to the fixation device.

Orthopedic fixation devices, both internal and external, are frequently coupled to bone by the use of fasteners such as screws, threaded bolts or pins. For example, bone plates can be secured to bone with bone screws, inserted through plate holes. Securing the screws to the plate provides a fixed angle relationship between the plate and screw and reduces the incidence of loosening. One method of securing the screw to the plate involves the use of so-called "expansion-head screws." U.S. Pat. No. 4,484,570 discloses an expansion-head screw with a head that has a recess, the walls of which contain a number of slits. After the expansion-head screw is inserted into bone through a hole in the fixation device, a locking screw is inserted into the recess to expand the walls of the recess to thereby lock the screw to the fixation device (such as a plate, internal fixator, nail, or rod). Another method of securing the screw to the plate involves the use of conical heads as shown in U.S. Pat. No. 5,053,036, which discloses conical screw holes, adapted to receive screws having conical heads of a predetermined cone angle, such that the plate will not slide down the heads of the screws. A third method of securing the screw to the plate involves the use of so-called "locking screws." A locking screw has threading on an outer surface of its head that matches with corresponding threading on the surface of a plate hole to lock the screw to the plate. Bone plates having threaded holes for

accommodating locking screws are known.

In addition to securing the screw to the fixation device, it is also often desirable to insert the screws at an angle relative to the fixation device selected by the surgeon. The prior art discloses a number of these so-called "polyaxial" systems, most of which utilize a bushing located in a hole in the fixation device to provide for locking at different degrees of angulation of the screw relative to the fixation device. For example, U.S. Pat. No. 5,954,722 discloses a polyaxial (selected variable axis) locking plate that includes a plate hole having a bushing rotatable within the hole. As a screw is being inserted into bone through the bushing and plate hole, a threaded tapered head of the screw engages a threaded internal surface of the bushing to expand the bushing against the wall of the plate hole, thereby friction locking the screw at the desired angular orientation with respect to the plate. U.S. Pat. No 6,575,975 discloses a polyaxial locking plate that includes a plate hole, having a a bushing rotatable within the hole, a fastening screw and a locking screw. The head of the fastening screw includes a radial wall that allows for outward expansion so that outwardly expanding the sidewall of the bushing so that the fastening screw is locked to the bushing and fixation device.

Some others of the so-called “polyaxial” systems utilize a ring located in a hole in the fixation device. For example, U.S. Pat. No 6,454,769 discloses a plate system and method of fixation comprising a bone plate, a bone screw and a ring, said ring being expandable against the bone plate to fix the bone screw at a selected angle relative to the bone plate.

These multi-component traditional plate assemblies can be cumbersome and tedious to manipulate during surgery to achieve the most desirable angle for directing the bone screw into the patient.

The present invention relates to an improved locked bone fixation assembly that allows for a surgeon-selected angle of a bone screw relative to the fixation device in only one single surgical action and using only two components, plate and screws, so that no rings, bushing or expansion head screws are longer needed.

BRIEF SUMMARY OF THE INVENTION

Is therefore an object of the present invention to provide a simple effective and strong locking mechanism for locking the bone screw to the fixation device.

Another object of the present invention is to provide a new and novel method of fixation, having a polyaxial coupling of the screw to the fixation device, whereby a single fixation device is compatible with a wide range of screw-in angles.

Further, it is an object of the present invention to provide a method of bone fixation, which provides the surgeon with the greatest freedom to choose the most desirable angle to direct the bone screw while maintaining an effective locking mechanism.

The present invention by being an easy and straightforward procedure for the surgeon makes bone fixation simple and fast overcoming one of the most important subject of matter of actual surgery, time shortening.

By fulfilling the recently mentioned objects, the present invention is extremely helpful to the medical care area.

The preferred embodiment of the present invention provides: a bone fixation device with through hole with an hourglass shape, made by the combination of a partial sphere and two frustoconical holes, to which

a number of isolated protrusions are coupled into; a bone screw with a threaded shank and a threaded head shaped as a partial sphere; wherein the bone screw can be threaded into the bone through the hole of the fixation device in only one single surgical action, solidly locking itself against the protrusions of the inner wall of the hole of the fixation device after being tightened; and wherein said bone screw can be inserted through the bore hole of the fixation device at variable orientations. The bone screw has an insertion/extraction hole on which the insertion /extraction tool is connected for the insertion/extraction of the bone screw into/from the bone, through the plate hole.

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Preferred features of the present invention are disclosed in the accompanying drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

FIG. 1 shows a perspective view of a bone fixation assembly according to the present invention wherein a 4 holes bone plate and a threaded spherical screw prior to insertion in the bone plate are shown.

FIG. 2 is a perspective view of a spherical headed screw.

FIG. 3 is a front view of the bone fixation assembly with two separated screws, each of which locks in a different angle with respect to the plate, and wherein the bone plate was removed to best shown the locking position of the screw.

FIG. 4 is a perspective view of a plate hole according to the present invention.

FIG. 5 is a perspective sectional view, at 1A-1A of FIG. 4, of the plate hole.

FIG. 6 is a front sectional view, at 1A-1A of FIG. 4, of the plate hole.

FIG. 7 is a perspective view of a bone fixation assembly according to the present invention wherein the screw is perpendicularly locked to the

bone plate, and wherein the anterior half of the plate has been shifted to the front to allow a better view of the locking system.

FIG. 8 is a perspective view of a bone fixation assembly according to the present invention wherein the screw is locked at a tilt, and wherein the anterior half of the plate has been shifted to the front to allow a better view of the locking system.

FIG. 9 is a front view of a bone fixation assembly according to the present invention wherein the screw is perpendicularly locked, and wherein the anterior half of the plate has been removed to allow a better view of the locking system.

FIG. 10 is a front view of a bone fixation assembly according to the present invention wherein the screw is locked at a tilt, and wherein the anterior half of the plate has been removed to allow a better view of the locking system

DETAILED DESCRIPTION OF THE INVENTION

Hereinafter, a method of bone fixation according to the preferred embodiment of the present invention will be explained with reference to FIGS 1 - 10.

The bone plate 1 shown in FIG. 1 comprises substantially an upper side 2 and a lower side 3 intended to be closer to the bone than the upper side 2, and a number of plate holes 5 that extend from upper 2 side to lower side 3.

As best shown in FIG. 2, the screws 7 have a head 8 and a shank 9. The head 8 is shaped like a sphere and is threaded with a constant pitch substantially equal to the pitch of the threaded shank 9, and wherein an insertion/extraction hole 10 is cut for the connection of the insertion/extraction tool. The thread cut in the screw head 8 has a double entry, keeping substantially the same pitch of the thread of the shank 9. The thread profile may vary according to the requirements and according to the mechanical properties of the used alloy.

FIG. 3 shows a circle 11 as a projection of the sphere from where the thread at the screw head 8 was cut showing that the angle of the screw 7 with respect to the bone plate 1 does not affect the position of the thread of the screw head 8 with respect to the walls of the plate hole 5.

As best seen in **FIGS. 4, 5, and 6** the section of plate holes **5** has an hourglass shape. The plate holes **5** are cut out of the bone plate **1** in a spherical shape, with both edges removed in a frustoconicaly shape. The easiest way to understand the shape of the plate holes **5** is to imagine two frustoconical holes connected by its tips through a partial sphere. The inner wall of each plate hole **5** has a small number of isolated protrusions **6** (such as pegs or spikes), which number is within 2 and 30, designed to lock against the threaded spherical head of the screws **8** when the said screws **7** are driven in through the said plate holes **5**. The protrusions **6** in the preferred embodiment are somehow flattened, having a width bigger than its length.

As it is shown in **FIGS. 7, 8, 9, and 10** once the screw **7** has been driven in, it locks tightly against the protrusions **6** existing in the plate holes **5**. It does not matter if the screw **7** was introduced perfectly perpendicular or at a tilt, the locking happens exactly the same way, only in different positions. This is possible because of the spherical shape of the screw head **8** allowing a good fit among the thread of the screw head **8** and the protrusions **6** in either perpendicular or tilted position. The amount of tilting accepted by this system varies according with the design. In the preferred embodiment shown through **FIGS. 1 to 10**, up to 20 degrees of angulation in any direction is allowed.

While I have illustrated and described a preferred embodiment of the invention, it will be understood that those skilled in the art will thereby be enabled to devise variations and modifications without departing from the spirit and scope of this invention, as defined in the appended claims. For

example, the plate hole **5** of the fixation device could be a combination of a few frustocones. A screw **7** with its head shaped like a sphere, can be used in conjunction with a bone fixation device with a through hole **5** with a shape generated by a combination of a few frustocones. The same applies if a screw **7** with its head generated by a rotating polygonal line and a fixation device with its holes **5** cut out in a spherical shape are used. The protrusions **6** included on the inner wall of the plate hole **5** could be round instead of being flattened protrusions **6**. Another variation could be related to the circular cross section of the protrusions **6** included on the inner wall of the plate hole **5** having the same width and length.

It must be noted that in every feasible embodiment, the hourglass shape of the plate hole **5** is mandatory in order to allow space for the screw **7** to be inserted at a tilt.